

DNAG-310-US (10509971)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Leyen, et al.
Serial No. : 10/549,731 – Conf. #1384
Filed : October 25, 2006
For : POLYLOCK INSERT FOR AN ARTIFICIAL HIP JOINT
Art Unit : 3738
Examiner : J-D. Neilken Stewart

October 6, 2010

Commissioner for Patents
P.O. Box 1450
Alexandria, VA. 22313-1450

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VA. 22313-1450 on the date shown below:

Jani M. Kelley 10/6/10
Signature Date

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

As required under 37 C.F.R. § 41.37(a), this brief is filed within two months of the Notice of Appeal filed in this case on August 6, 2010, and is in furtherance of said Notice of Appeal. Please charge the required fees under 37 C.F.R. § 41.20(b)(2) to Deposit Account no. 50-0624.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1206:

- I. Real Party In Interest
- II. Related Appeals and Interferences
- III. Status of Claims
- IV. Status of Amendments
- V. Summary of Claimed Subject Matter
- VI. Grounds of Rejection to be Reviewed on Appeal
- VII. Argument
- VIII. Claims Appendix
- IX. Evidence Appendix
- X. Related Proceedings Appendix

I. REAL PARTY IN INTEREST

The real parties in interest for this appeal is the assignee, CERAMTEC AG, Innovative Ceramic Engineering.

II. RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Total Number of Claims in Application

There are 11 claims (numbered claims 35-45) presently pending in this application.

Current Status of Claims

Claims canceled: 1-34

Claims pending: 35-45

Claims allowed: None

Claims rejected: 35-45

Claims On Appeal

The claims on appeal are all rejected claims, i.e., claims 35-45.

IV. STATUS OF AMENDMENTS

All amendments are believed to have been entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

With reference to Figure 1, the subject matter relates to a hip joint prosthesis having a ceramic inner sliding cup (1), which is surrounded on its outside by a plastics covering (2), for insertion into an outer metal cup (6) or for direct implantation with the aid of bone cement (see also e.g. page 4, lines 5-11; page 5, lines 13-18). A ball head, which is mounted on a shaft, articulates inside the inner sliding cup (1) (see e.g. page 5, lines 19-21). Said shaft can be anchored in the femur (see e.g. page 5, lines 21-22). To increase the strength with respect to tilting and turning, the exterior of the sliding cup (1) is provided with a structuring (see also e.g. page 2, lines 17-23). The presently claimed hip joint prosthesis achieves a high level of strength with respect to tilting or turning with a small amount of contruction space being required (see e.g. page 2, lines 14-16 and lines 17-23)

A. Independent Claim 35

Independent claim 35 is directed to a hip joint prosthesis having a ceramic inner sliding cup, a plastic covering which receives the inner sliding cup, and an outer metal cup (see for example, page 4, lines 5-11 and lines 14-15). As set forth in claim 35, the sliding cup has a plurality of depressions on an outside (see e.g., Fig. 3; page 4, lines 28-32; page 5, lines 7-8). The plastic covering has corresponding plurality of raised structures, which are received by said depressions (see e.g. Fig. 3).

B. Independent Claim 45

Independent claim 45 is directed to a hip joint prosthesis having a ceramic inner sliding cup (see e.g. Fig. 1; page 4, lines 5-7). The sliding cup has an outer surface, which is surrounded by a plastic covering (see e.g. Figs. 1 and 2; page 4, lines 7-8 and lines 14-15). According to claim 45, the outer surface of the sliding cup has a plurality of structuring features on it (see e.g. Fig. 3; page 2, lines 17-19; page 4, lines 30-32).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether the Examiner erred in finally rejecting claims 35-41, 43 and 44 under 35 U.S.C. §103(a) for allegedly being unpatentable over WO 01/05338 (“Bunz”) in view of U.S. Patent No. 6,676,704 (“Pope”) and U.S. Published Application No. 2004/0054418 (“McLean”).

2. Whether the Examiner erred in finally rejecting claim 42 under 35 U.S.C. §103(a) over Bunz, Pope, McLean and U.S. Patent No. 5,041,140 (“Teinturier”).

3. Whether the Examiner erred in finally rejecting claim 45 under 35 U.S.C. §103(a) over Bunz in view of Pope.

Appellants submit that the Examiner did err in making these rejections.

VII. ARGUMENT

1. Rejection of claims 35-41, 43 and 44 over Bunz in view of Pope and McLean

An invention that would have been obvious to a person of ordinary skill at the time of the invention is not patentable. See 35 U.S.C. 103(a). As reiterated by the Supreme Court in KSR, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (A) Determining the scope and content of the prior art; and
- (B) Ascertaining the differences between the claimed invention and the prior art; and
- (C) Resolving the level of ordinary skill in the pertinent art.

Bunz teaches to use a single stem in such a way that a high level of strength with regard to tilting is achieved. According to Bunz, however, a large amount of construction space is required, because there is only one stem which has to be large enough to avoid a tilting movement sufficiently.

In the present application the outside of the sliding cup has a plurality of undulations. Each undulation acts to avoid tilting and for each undulation only a relatively small amount of construction space is required. The high level of strength with regard to tilting is achieved because of the plurality of undulations. Each undulation alone is not sufficient to avoid tilting.

The Examiner alleges that Pope discloses “a substrate for attachment to a femoral head and an acetabular [sic] comprising of spherical segment depressions with a diameter from .001 in. up to .750 in. (col. 43, lines 15-35) undulating in section, and circumferentially arranged (fig. 3c) for the purpose of creating a mechanical interlock between adjacent layers of the hip prosthesis (col. 45, lines 13-16). The Examiner concludes that it would have been obvious to

modify the sliding cup of the sandwich insert of Bunz with the undulating depression of Pope in order to achieve mechanical interlock as taught by Pope (citing Col. 45, lines 13-16).

It appears, however, that the Examiner has construed the purpose for which Pope provides the undulating section somewhat broadly, as the passage at Col. 43, lines 15-35 only teaches that surface modifications 353 were formed on the surface of sphere 350, which is a substrate which will receive the polycrystalline diamond layer, to increase the numbers of chemical bonds between the substrate and the diamond table to achieve a stronger polycrystalline diamond compact. (See Col. 41, lines 18-22).

Furthermore, Col. 41, lines 23-27 disclose that the substrate surface topographical features also serve to create a mechanical interlock between the substrate and the diamond table, and not merely between a sliding cup of a sandwich insert as disclosed by Bunz, and presumably, the outer surface of the inner sliding cup of Bunz.

The bonding between the polycrystalline layer and the substrate of Pope is clearly different than the connecting of two individual components, i.e., the inner sliding cup and the outer sliding cup of Bunz.

Since the sole purpose of providing surface features to a substrate of Pope is to receive a polycrystalline diamond layer, one of skill in the art would not modify the surfaces of the components of Bunz's prosthesis as suggested by the Examiner.

Furthermore, Pope sinters the polycrystalline layer to the substrate. Since Bunz's outer shell is plastic, one of skill in the art would not be led to combine Bunz with Pope since sintering as taught by Pope may deform or even destroy the plastic.

Thus, this rejection must be withdrawn.

2. **Rejection of claim 42 over Bunz, Pope, McLean and Teinturier.**

Arguments above apply equally here and are incorporated by reference.

Teinturier is cited by the Examiner for allegedly disclosing a press fit between a plasmic cup and a metal shell. Teinturier, however, fails to overcome deficiencies of the primary combination of Bunz, Pope and McLean. Thus, this rejection must be withdrawn.

3. **Rejection of claim 45 over Bunz in view of Pope.**

Arguments above apply equally here and are incorporated by reference.

It is emphasized that since the bonding between the polycrystalline layer and the substrate of Pope is clearly different than the connecting of two individual components, i.e., the inner sliding cup and the outer sliding cup of Bunz, one of skill in the art would not modify the surfaces of the components of Bunz's prosthesis as suggested by the Examiner. Thus, this rejection should be withdrawn.

For the foregoing reasons these rejections cannot stand.

VIII. CLAIMS APPENDIX

A copy of the claims involved in the present appeal is attached hereto as Appendix A.

IX. EVIDENCE APPENDIX

No evidence pursuant to §§ 1.130, 1.131, or 1.132 or entered by or relied upon by the examiner is being submitted.

X. RELATED PROCEEDINGS APPENDIX

No related proceedings are referenced in II. above, hence copies of decisions in related proceedings are not provided.

A favorable decision reversing the Examiner on all rejections is earnestly solicited.

Dated: October 6, 2010

Respectfully submitted,

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APPENDIX A

CLAIMS APPENDIX
(37 C.F.R. § 41.37(C)(VIII))

Claims 1-34 (canceled)

35. A hip joint prosthesis comprising:

an inner sliding cup, said inner sliding cup comprising a ceramic material;

a plastic covering which receives said inner sliding cup; and

an outer metal cup,

wherein said sliding cup has a plurality of depressions on an outside and wherein said plastic covering has corresponding plurality of raised structures that are received by said plurality of depressions.

36. A hip joint prosthesis according to claim 35, wherein the plurality of depressions undulate in section.

37. A hip joint prosthesis according to claim 36, wherein the plurality depressions are circumferentially arranged on the outside of the sliding cup.

38. A hip joint prosthesis according to claim 35, wherein the plurality depressions are semicircular.

39. A hip joint prosthesis according to claim 35, wherein the sliding cup has on its outside a spherical or stepped structural form.

40. A hip joint prosthesis according to claim 35, wherein the plastic covering embraces the sliding cup at its end.

41. A hip joint prosthesis according to claim 40, wherein the plastic covering has a collar that rests on the upper side of the sliding cup and covers almost half of upper edge thereof.

42. A hip joint prosthesis according to claim 35, wherein the sliding cup is pressably connected to the plastic covering.

43. A hip joint prosthesis according to claim 35, wherein the inner form of the sliding cup is arranged eccentrically in relation to the outer form of the sliding cup.

44. A hip joint prosthesis according to claim 43, wherein variation with respect to the coaxiality is at least 0.001mm.

45. A hip joint prosthesis comprising an inner sliding cup made of a ceramic material and having an outer surface; and

another plastic covering surrounding the outer surface of the inner sliding cup;

wherein the outer surface of the sliding cup has a plurality of structuring features thereon.

APPENDIX B
EVIDENCE APPENDIX

None.

APPENDIX C

RELATED PROCEEDINGS APPENDIX

None.